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EXAMINER	
VAINBERG, SIMON	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,055	LINDENBERG, SVEND	
	Examiner	Art Unit	
	Simon Vainberg	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *227-243* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *227-243* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 227, 228, 231, 234, 235, 237 and 238 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830) in view of Lindenberg et al. (WO99/67365) and further in view of Ellington et al. (US Patent 6140121).

Regarding claim 227, Findley et al. teaches a system for in vitro producing a mammalian pre-embryo (see column 1 lines 7-10), said system comprising an apparatus 11 (called incubator, see column 3 line 39) having at least two separate air- tight chambers (13) and 57 (called airlock) (see Fig. 3 and column 3 line 40 and column 6 line 41), for which the oxygen tension of one chamber may be changed independent of the oxygen tension of the other chamber (see claim 3, which teaches

the means for controlling the concentration (tension) of oxygen in within a chamber (13), and column 7 lines 5-10 disclosing the means for maintaining the oxygen concentration in airlock chamber independent from chamber (13)) said at least two separate air-tight chambers constitute a main chamber(15) (called enclosure, see Fig. 3 and column 3 line 41) and at least one residence chamber (68) (called storage compartment, see column 7 lines 29-33, and Fig. 6) , where said at least one residence chamber (68) are smaller than said main chamber (15) and are located inside the main chamber (see Fig. 6), said apparatus comprising at least one entrance port (59) (called internal door of air lock) capable of communicating with the means for obtaining the mammalian oocyte and/or the mammalian spermatozoa, and

an exit port for withdrawal of the pre-embryo (61) (called external door of air lock, see column 6 lines 37-43 and Fig.3),

as well as a communication port (59) (called internal door) between said at least two chambers allowing transfer of oocyte, spermatozoa and/or pre-embryo between the chambers (see column 6 lines 40-42 and Fig. 3 or Fig. 4).

Findley et al. does not teach the means for obtaining a mammalian oocyte, and means for obtaining a mammalian spermatozoa.

Lindenberg et al. teaches the means for obtaining a mammalian oocyte (17g Cook needle, syringe and tube) (see page 11 lines 5-70), but mute about means for obtaining a mammalian spermatozoa.

Ellington et al. teaches the means for obtaining sperm comprising tubes, a 27 gauge needle and 1 ml syringe (see column 14 lines 44-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teaching of Findley et al. by including means for obtaining a mammalian oocyte as taught by Lindenberg and sperm as taught by Ellington et al. because it allows to conduct the IVF procedure.

Examiner interpreted claim 227 according to 35 USC 112, six paragraph.

Regarding claim 228, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein the means for obtaining a mammalian oocyte is a system with a needle communicating under airtight conditions with a means for transferring from needle to said apparatus, such means for transferring comprises syringe and tube.

Findley et al. teaches air- tight apparatus with air-lock (see column 2 lines 58- 62 and Abstract).

Lindenberg et al. teaches means for obtaining a mammalian oocyte comprising syringe, needle and tube and means for transferring comprising syringe and tube (see page 11 lines 44-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al. and Ellington et al. by including a syringe, needle and tube as taught by Lindenberg et al. because it allows to prevent a damage and contamination of the oocyte of during IVF procedure.

Regarding claim 231, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein the oxygen tension of each other chamber is regulated independently by adding oxygen, nitrogen, carbon dioxide, helium or

another inert gas, or a mixture of two or more of these gasses simultaneously with removing gas from the chambers, in the way that the pressure of the air is in accordance with the atmosphere.

Findley et al. teaches that incubator includes sensors for determining the oxygen concentration within the chamber and means for adding carbon dioxide, nitrogen or oxygen to the ambient gas within the incubator in order to maintain the desired level of oxygen (see Abstract). Findley et al. further teaches that airlock may include means for coupling thereto a source of gas for controlling the composition of the gas within the airlock. (see column 3 lines 12-15).

Regarding claim 234, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein a microscope can be placed and used when handling the oocytes, spermatozoa and embryos.

Findley et al. teaches a microscope (23) is placed in a chamber (13) (see column 4 lines 9-13).

Regarding claim 235, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein a working area is obtained within said main chamber, said working area comprises a place for culturing means containing the cultured cell structures, where the cultured cell structures is observed in the microscope, and said working area comprises room for handling means.

Findley et al. teaches a working area inside of a main chamber comprising a place for culturing means (shelves (53) and (55)) (see Fig. 2 and column 6 lines 13-20), interior platform and storage compartment (68) (see column 7 lines 27-33).

Regarding claim 237, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein the main chamber comprises opening means permitting entrance to human to handle the cell culture or the equipment inside the chambers.

Findley et al. teaches that access by user to the interior of the chamber (13) is provided by the hand openings (17) in the front face of the enclosure (15).(see column 3 line 67 through column 4 line 8). Findley et al. further teaches that other hand openings may be provided in the back or side walls of the enclosure (15) as desired. (see column 4 lines 16-22).

Regarding claim 238, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 237, wherein to the opening means is attached instruments manipulated by fibre optics, by which the cell culture or the equipment can be handled.

Findley et al. teaches that the light is delivered to the microscope stage (25) through fiber optic cable (53) by light source (51) attached to the chamber in order to prevent the heat generated by light source (see column 6 lines 9-12 and Fig. 2).

4. Claim 229 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830), Lindenberg et al. (WO99/67365) and Ellington et al. (US Patent 6140121), as applied to claim 227 in view of Burkman (Burkman L. J. A Microperfusion Chamber for study of Mammalian Spermatozoa. 1988. Journal of Andrology, v. 9, p. 102-108).

Regarding claim 229, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227, wherein the means for obtaining a mammalian spermatozoa is a system in which the oxygen tension can be controlled.

Ellington et al. teaches a means for obtaining a mammalian sperm comprising syringe. Ellington et al. does not teach a gas tight syringe.

Burkman teaches a chamber for study of mammalian spermatozoa and discloses using a gas tight syringe instead of plastic syringe to eliminate lost of carbon dioxide from medium (see page 106 right column lines 9 and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by using a gas tight syringe as taught by Burkman because it allows to eliminate the loss of CO_2 from medium.

5. Claim 230, 232 and 233 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830), Lindenberg et al. (WO99/67365) and Ellington et al. (US Patent 6140121), as applied to claim 227, in view of Orchard et al. (US Patent 5169217).

Regarding claim 230, Findley et al, Lindenberg et al. and Ellington et al. teach the system according to claim 227, except the temperature of each chamber can be regulated independently.

Findley et al. teaches a temperature controlled chamber 13 (see column 4 lines 28-30).

Findley et al. does not teach that the temperature another chamber can be controlled independently.

Orchard et al. teaches a controlled environment chamber apparatus for maintaining biological material under controlled conditions of temperature (see claim 1). Orchard further teaches an apparatus comprising two self-contained incubators (2A and 2B) each with its own control panel (see column 3 lines 10-12) that inherently indicates on individual temperature control of each incubator.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by fabricating chambers with two separate temperature controls as taught by Orchard et al. because it allows to more precisely control the temperature in each incubator or maintain the cells at different temperature conditions.

Regarding claim 232, Findley et al, Lindenberg et al. and Ellington et al. teach the system according to claim 227, except the humidity of each chamber can be controlled and regulated to a level between 50 and 100%.

Findley et al. teaches a humidification system to maintain the high level of humidity (90-95%) in the chamber (13) (see Abstract and column 5 lines 43 and 64 through column 6 lines 3).

Findley et al. does not teach that the humidity of each chamber can be controlled and regulated to a level between 50 and 100%.

Orchard et al. teaches a controlled environment chamber apparatus for maintaining biological material under controlled conditions of humidity (see claim 1).

Orchard further teaches an apparatus comprising two self-contained incubators (2A and 2B) each with its own control panel (see column 3 lines 10-12) that inherently indicates on individual humidity control of each incubator.

Orchard et al. does not teach directly that each chamber can be controlled and regulated to a level between 50 and 100%.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made that most of the incubators with a humidity control are capable to maintain the level of relative humidity between 50 and 100%.

It also would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by fabricating chambers with two separate humidity controls as taught by Orchard et al. because it allows to more precisely control the humidity in each incubator or maintain the cells at different level of relative humidity.

Regarding claim 233, Findley et al, Lindenberg et al., Ellington et al. and Orchard et al. teach the system according to claim 232, wherein said entrance port and said exit port are combined to an air lock and the atmosphere of said air lock can be controlled and adjusted in respect of the contents of oxygen, nitrogen, carbon dioxide, helium or another inert gas, and in respect of the temperature and humidity.

Findley et al. teaches an airlock (57) which includes entrance port (59) (called inner door) and exit port (61) (called external door) (see column 6 lines 37- 44) and the atmosphere of said air lock can be controlled and adjusted (see column 3 lines 12-

15). Findley et al. does not teach that the atmosphere of air lock can be controlled and adjusted in respect of the temperature and humidity.

Orchard et al. teaches a controlled environment chamber apparatus for maintaining biological material under controlled conditions of temperature and humidity (see claim 1). Orchard further teaches an apparatus comprising two self-contained incubators (2A and 2B) each with its own control panel (see column 3 lines 10-12) that inherently indicates on individual temperature and humidity control of each incubator.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by fabricating a separate temperature and humidity control system in another chamber as taught by Orchard et al. and adjust the atmosphere of this chamber in respect of the temperature and humidity.

6. Claim 236 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830), Lindenberg et al. (WO99/67365) and Ellington et al. (US Patent 6140121) as applied to claim 235 in view of Ranoux et al. (US Patent 6050935).

Regarding claim 236, Findley et al, Lindenberg et al. and Ellington et al. teach the system according to claim 235, except a micro-insemination apparatus is placed within the main chamber.

Findley et al. teaches an airlock for allowing the easy transfer of biological materials and other equipment to the chamber (13)(see column 6 lines 38-40).

Findley et al. does not teach directly that a micro-insemination apparatus is placed in a chamber.

Ranoux et al. teaches a micro-insemination apparatus (called container for intravaginal fertilization) (see Abstract and column 1 lines 10-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by placing in a chamber the equipment for IVF procedure including a micro-insemination apparatus as taught by Ranoux et al. because it allows to conduct the procedure at optimal conditions.

7. Claims 239 and 240 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830), Lindenberg et al. (WO99/67365) and Ellington et al. (US Patent 6140121), as applied to claim 227 in view of Vajta (US Patent 6399375) .

Regarding claim 239, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 237 except the main chamber has at least one small part of its surface replaced with a membrane, said membrane is sterile and has a structure through which a needle can be struck through, when the needle is removed said membrane fills up the area where the needle stuck was through, and no gasses or particles can diffuse through the membrane either when a needle is stuck through the membrane or no needle is stuck through the membrane.

Vajta teaches an incubator containers fabricated from gas and liquid impervious, flexible, sealable, preferably transparent bags for cells and tissues, in particular sensitive cells and tissues, such as oocytes, fertilized oocytes and preimplantation embryos, which require highly stable physical and chemical environment for in vitro

development (see Abstract). Vajta further teaches that instead of the inlet (116) and outlet (118) the bag can be provided with one or more selfsealing membranes (120), e.g. rubber septums, sealed to the wall of the bag with a ring-shaped sealing stripe (121) or optionally with a circular sealing layer provided between the membrane and the wall of the bag. The presealed bag can then be filled with the proper gas mixture through a sterile injection needle passed through the membrane (which is also inherently sterile) into the interior volume of the bag. When retracting the needle the puncture hole made by the needle will be closed automatically due to the selfsealing membrane material (see column 13 lines 41-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by placing a selfsealing membrane on the surface of the container as taught by Vajta because it prevents the contamination of the container and allows to maintain the required concentration and pressure of the gasses in the container.

Regarding claim 240, Findley et al., Lindenberg et al., Ellington et al. and Vajta teach the system according to claim 239, wherein said residence chambers constitute boxes for culture containers containing cell cultures of oocyte, spermatozoa, embryo, and stem cells including stem cell lines.

Findley et al. teaches residence chambers (68) (called storage compartments), which constitute boxes for culture dishes and other items within the chamber (13) (see column 7 lines 29-33 and Fig. 5 and 6). Findley et al. further teaches that biological material includes cells, tissues and organisms (see column 1 lines 6-9).

8. Claim 241 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findley et al. (US Patent 4892830), Lindenberg et al. (WO99/67365) and Ellington et al. (US Patent 6140121), as applied to claim 227 in view of Campbell et al. (US 20020068358).

Regarding claim 241, Findley et al., Lindenberg et al. and Ellington et al. teach the system according to claim 227 except the oxygen tension and pressure of each chamber or air-tight boxes can be regulated by a computer by retrieving an image of the embryo in said chamber or said air-tight boxes.

Campbell et al. teaches in vitro embryo assembly which includes the control system of the embryonic support assembly configured for regulating one or more conditions within the container (called well) according to a predetermined set of instructions (e.g., one or more sets of computer-readable instructions or algorithms stored in a memory which is in communication with the processor) (see paragraph 0019). The embryonic support assembly may further be configured for periodically acquiring data concerning one or more conditions within the well and storing such data in the memory and/or transmitting such data to an external device (see paragraph 0020). A control system for regulating one or more conditions within the wells may also be included, along with a plurality of imaging devices wherein each of the imaging devices is configured for acquiring image data of an embryo located within one of the wells (see paragraph 0045 and also paragraphs 0097 and 0098). Campbell et al. further teaches that control system comprises at least one sensor chosen from the group consisting of an oxygen sensor, a carbon dioxide sensor (see claim 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Findley et al., Lindenberg and Ellington et al. by installing a image reading control system which can be able to analyze the image of embryo and concentration of oxygen in a container, compare it with the stored computer data and send a corresponding signal to a regulated device as taught by Campbell et al. because it allows to maintain the required level of oxygen in container based on condition of the embryo.

It also would have been obvious to one having ordinary skill in the art at the time the invention was made to use a well known control image system to regulate different parameters of the system including oxygen concentration and pressure.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 242 and 243 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 242 provides for the use of the system according to claim 227, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 242 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 243 provides for the use of the system according to claim 227, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 243 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon Vainberg whose telephone number is 571-270-3150. The examiner can normally be reached on Monday- Thursday 7:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SV

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